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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,075

02/20/2007

Jobst Krauskopf

19491

5999

272

7590

09/01/2010

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

09/01/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,075	<b>Applicant(s)</b> KRAUSKOPF ET AL.	
	<b>Examiner</b> Ruth A. Davis	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

Applicant's Request for Continued Examination and IDS filed on June 23, 2010 have been received and entered into the case. Claims 1 – 14 are pending and have been considered on the merits.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 – 5, 7 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Reimer et al. (US 2003/0004095).

Reimer teaches a method for treating diabetes and secondary diseases thereof (abstract, 0002, 0008) comprising administering sweet whey permeate (0034, 0047), wherein glucose homeostatis (or glucose intolerance) (0009) and secondary diseases such as kidney failure or cardiovascular disorders or improved (0008). The whey is delactosed (or reduced in lactose) (0037), is orally administered as a powder, juice, or food (0057, example 8), or may contain pharmaceutically acceptable additives or carriers (example 5).

The reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimer (US 2003/0004095).

Reimer teaches a method for treating diabetes and secondary diseases thereof (abstract, 0002, 0008) comprising administering sweet whey permeate (0034, 0047), wherein glucose homeostatis (or glucose intolerance) (0009) and secondary diseases such as kidney failure or cardiovascular disorders or improved (0008). The whey is delactosed (or reduced in lactose) (0037), is orally administered as a powder, juice, or food (0057, example 8), or may contain pharmaceutically acceptable additives or carriers (example 5).

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Reimer does not specifically teach the composition wherein it is microencapsulated, wherein the patient is human, or wherein the permeate is hydrolyzed or partially hydrolyzed. However, the reference suggests administering the composition enterally (example 5). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to encapsulate an enteral composition as it was routine to do so in the art at the time of the claimed invention. Furthermore, while the reference does not expressly state the method is for humans, one in the art would understand that the reference suggests the method for treating humans. Finally, it is noted that the reference does teach protein hydrosylates (entire ref). Although the reference does not teach a hydrolyzed whey permeate, it would have been within the purview of one of ordinary skill in the art to use such a permeate in following the teachings of Reimer as it suggests hydrolyzed proteins for use in the methods of treating diabetes. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the teachings of Reimer to use a hydrolyzed whey permeate in the methods of Reimer with a reasonable expectation for successfully treating diabetes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651

August 29, 2010